



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,763	09/26/2003	David J. Yang	UTSC:664USC1	1049
32425	7590	11/04/2005	EXAMINER	
FULBRIGHT & JAWORSKI L.L.P. 600 CONGRESS AVE. SUITE 2400 AUSTIN, TX 78701			JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	
DATE MAILED: 11/04/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/672,763

Applicant(s)

YANG ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-58, 61-66 and 79 is/are rejected.
- 7) ☒ Claim(s) 59, 60, 67-78 and 80-82 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1618

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 8/10/05 wherein claims 1-51 are canceled.

Note: Claims 52-82 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

2. The Applicant's arguments filed 8/10/05 to the rejection of claims 52-58, 61-64, 66, 67, 69, 70, and 79 made by the Examiner under 35 USC 102 and/or 103 have been fully considered and deemed persuasive. Therefore, all outstanding rejections are WITHDRAWN for reasons of record in Applicant's response.

NEW GROUNDS OF REJECTIONS

102 Rejections

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 52, 53, 55, 63, and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson et al (Nucl. Med. Biol., 1995, Vol. 22, No. 2, pages 165-173).

Art Unit: 1618

Anderson et al disclose N,N'-ethylene-di-L-cysteine (EC) complexes of Ga (III) and In(III). The chelates contain two nitrogens and two sulfurs (N₂S₂). N,N'-ethylene-di-L-cysteine is a N₂S₂ ligand that also contains two carboxylic acid moieties for complexation of Ga(III) and In(III). The ⁶⁸Ga-EC complex are possible myocardial PET imaging agents. The radiolabeled complex was injected into rat and various tissues and organs (e.g., lung, liver, and brain) were observed (see entire document, especially, abstract; page 167-168, bridging paragraph; page 171, Table 5; page 172, Table 6). Thus, both Anderson et al and Applicant disclose a method of imaging a site within a subject wherein a radionuclide labeled bisaminoethanethiol (BAT) targeting ligand conjugate is administered to a subject.

5. Claims 52, 54-56, 58, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Kung et al (J. Med. Chem., 1985, Vol. 28, pp. 1280-1284).

Kung et al disclose bisaminoethanethiol (BAT) derivatives that are possible ligands for ^{99m}Tc brain imaging agents. The brain perfusion imaging agents may be analyzed by single photon emission computed tomography (SPECT) [see entire document, especially, page 1280, column 1; page 1284, column 1, 'Animal Distribution Study'). In Table II, page 1284, the biodistribution of ^{99m}Tc complexes in rats. In particular, the biodistribution of the labeled complex in the brain, lungs, and liver is disclosed. Thus, both Kung et al disclose methods of imaging a site within a subject wherein the subject is administered a radionuclide labeled bisaminoethanethiol targeting ligand conjugate.

Art Unit: 1618

6. Claims 52, 55, 56, 57, 58, 61, 62, 63, 66, and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by McBride et al (US Patent No. 5,620,675).

McBride et al disclose radioactive peptides that may be used as therapeutic or diagnostic agents for analyzing a mammalian body (see entire document, especially, abstract). In particular, in column 13, lines 18-21, it is disclosed that small linear synthetic peptides that are somatostatin analogues which incorporate bisamine bisthiol (BAT) chelators may also be labeled with Tc-99m. In addition, McBride et al disclose that the technetium-99m labeled imaging agents may be used for visualizing organs for tumors, myelomas, small cell lung carcinoma, and other Apudomas, thyroid carcinomas, pituitary tumors, brain tumors, and prostate, breast, colon, and ovary tumors (column 13, line 63 through column 14, line 16). Thus, it would be obvious to one of ordinary skill in the art to administer a radiolabeled bisaminoethanethiol (BAT) complex to a subject for imaging purposes.

103 Rejections

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1618

8. Claims 52, 57, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (Nucl. Med. Biol., 1995, Vol. 22, No. 2, pages 165-173).

Anderson et al (see discussion above) fail to specifically disclose a method of imaging wherein ^{68}Ga is utilized. However, it would have been obvious to one of ordinary skill in the art to use a ^{68}Ga labeled targeting agent because Anderson et al disclose that ^{68}Ga -EC has potential as a possible PET imaging agent (see the last line of the abstract). In addition, Anderson et al fail to disclose their conjugate being administered to a human. However, it would be obvious to administer the radiolabeled BAT conjugate to a human because both the rat and human are mammals, thus, one of ordinary skill in the art would be motivated to administer the labeled conjugate to various mammals.

9. Claims 52 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kung et al (J. Med. Chem, 1985, Vol. 28, pp. 1280-1284).

Kung et al (see discussion above) fail to disclose administering a radiolabeled BAT conjugate to a human. However, it would be obvious to administer the radiolabeled BAT conjugate to a human because both the rat and human are mammals, thus, one would be motivated to administer the radiolabeled conjugate to various mammals.

Art Unit: 1618

10. Claims 52, 54-56, 58, 61-63, 66, 69, and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Auzeloux et al (J. Labelled Cpd. Radiopharm., 1999, Vol. 42, pp. 567-579).

Auzeloux et al disclose Tc-99m bisaminoethanethiol (BAT) derivatives that has potential as a melanoma tracer agent. The radiolabeled BAT complexes were administered to a mice and various organs such as the liver, lung, and brain were analyzed (see entire document, especially, page 567, 'Summary'; page 568; page 568, third complete paragraph; page 569, Figure 3; page 572, 'Biological Results'; page 572, Table 3; page 578, 'Biological'). Thus, both Auzeloux et al and Applicant disclose a method of imaging a site within a subject a radionuclide labeled bisaminoethanethiol is administered to the subject.

CLAIM OBJECTIONS

11. Claims 59, 60, 67-78, 80-82 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The claims are distinguished over the prior art of record because the prior art neither anticipate nor renders obvious the limitations in combination with their respective intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'D. L. Jones', is positioned above the printed name.

D. L. Jones
Primary Examiner
Art Unit 1618

October 31, 2005